FILE

AUG 1 1980

Dr. Jon Rosenberg
Public Health Medical Officer
Hazard Alert System (HALTS)
State of California Department
of Health Services
2151 Berkeley Way
Berkeley, California 94704

Dear Dr. Rosenberg:

Thank you for your letter of June 27, 1980, enclosing for our review the report recently released by your Department evaluating the human health hazards of 2,4-D. Since your report has been the subject of a considerable amount of public attention, we appreciated this opportunity to review and respond to your interpretations of the available data on 2,4-D, particularly the reported case studies which indicate that neuropathological effects may be associated with direct 2,4-D exposure.

As you know, EPA also reviewed the available health effects studies on 2,4-D this past spring, and announced the results of that review on April 29. Essentially, the Agency decided that the toxicological studies performed to date do not indicate that serious adverse health effects are likely to result from the approved uses of 2,4-D. However, deficiencies were found in some existing studies, and significant information gaps were noted in several vital areas of health risk assessment including oncogenicity, reproductive effects, neurotoxicity and metabolism in animals. Because of these data gaps, EPA has been unable to reach a definite conclusion on the safety of 2,4-D thus far. The Agency is requiring that manufacturers of the herbicide repeat the inconclusive or deficient studies using acceptable test methods, and that they conduct some altogether new health effects testing. EPA may change its current regulatory position on 2,4-D, based on the results of this new information.

In reviewing your report on the health effects of 2,4-D, we noted that you considered basically the same studies that were available to and considered by EPA during our reassessment of 2,4-D's health risks. We were pleased to see that, for the most part, your conclusions regarding the anticipated health effects of 2,4-D were similar to ours. The single, notable exception was in the area of neurotoxicity. Although you considered the same seven case studies involving 2,4-D exposure and resulting neurotoxic effects that this Agency considered, you reached a different conclusion regarding the severity of the anticipated neurotoxicity risk posed by approved, routine uses of the herbicide. We at EPA are, as you know, also concerned about the potential neurotoxicity of 2,4-D. However, our interpretation of the available laboratory data and case studies leads us to the conclusion (for now, at least) that typical use of 2,4-D as directed on approved product labels is not expected to produce neuropathy in persons exposed. As with many registered pesticides, neuropathological symptoms may result from accidentally high degrees of exposure to 2,4-D, or among particularly susceptible persons. Because your report presented no new or original animal data, case studies, epidemiological work or exposure information, the report does not change EPA's current interpretation of the existing studies, perception of the additional data needed, or overall regulatory position on 2,4-D.

For your information, I am enclosing a set of tables listing the key studies considered by EPA in reaching its tentative regulatory position on 2,4-D. For each study, the author, study protocol, author's conclusions and EPA comments are briefly noted. The Agency plans at some time in the near future to make available a more complete report of its findings on 2,4-D as presented to our Scientific Advisory Panel in May. That report will expand upon the EPA comments briefly summarized in the enclosed tables. I will see that you are sent a copy of the more complete EPA report on 2,4-D, once it is available.

As the enclosed EPA press release and fact sheet discuss, the Agency is in the process of imposing some additional 2,4-D data development requirements in order to fill the current gaps in our knowledge about 2,4-D and its potential health effects. For example, we are requiring that 2,4-D manufacturers develop an additional neurotoxicity animal study, to fill the gaps in our present knowledge regarding that effect. In order

to properly interpret those experimental data, we realize that we must also have better information on expected human exposure to 2,4-D. Thus, EPA is closely examining all reported incidents involving human exposure to 2,4-D. We are also continuing to support field tests conducted by the U. S. Department of Agriculture and the University of Arkansas, measuring applicator exposure to 2,4-D during the present growing season. Based on the new animal studies and baseline human exposure data, EPA will be better able to assess the neurotoxicity and other potential health risks associated with 2,4-D use.

Thank you for sharing your interpretation of the available neurotoxicity and other toxicology data on 2,4-D with this Agency. Please be assured that we are committed to resolving the outstanding health and safety questions surrounding 2,4-D as quickly and effectively as possible. If I may be of further service, please feel free to contact me.

Sincerely yours,

Edwin L. Johnson
Deputy Assistant Administrator
for Pesticide Programs

Enclosures

AX-919 TSPX:CPSTANGEL:X58020:kt:7/25/80
cc: TS 788(2) AX
Anita Schmidt (SPRD - TS 791) w/inc
Hank Spencer (HED - TS 769) w/inc.

CONCURRENCES

SYMBOL	TSPX	TSPX	HED	SPRD				
SURNAME	Clanasewich	[illegible]	[illegible]	CP for AS:MW (see route slip)				
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EPA Form 1320-1 (12-70) W/changes

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STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY/AGRICULTURE AND SERVICES AGENCY EDMUND G. BROWN JR., Governor

DEPARTMENT OF HEALTH SERVICES/DEPARTMENT OF INDUSTRIAL RELATIONS
HAZARD ALERT SYSTEM (HALTS)
2151 BERKELEY WAY
BERKELEY, CA 94704

June 27, 1980

Ms. Barbara Blum
Deputy Administrator
United States EPA
401 M St. S. W.
Washington, DC 20460

Subject: 2,4-D

Dear Ms. Blum:

Enclosed is the report on the human health hazards of 2,4-D, just released by the California Department of Health Services. As its principal author, I am forwarding this to you for a number of reasons. While for the most part our conclusions are similar to those released on April 29, by the E.P.A., there are some differences.

The most significant relates to the possible neurotoxicity of 2,4-D. We personally investigated the case in Humboldt County, California, and in conjunction with thorough review of the six previously reported cases we strongly believe that 2,4-D is the causative agent.

Most of the points in support of this are contained in the document. Mitigating strongly against a coincidental association is the fact that many of the cases had a mild illness upon first exposure to 2,4-D, but developed a more severe illness following a second exposure. That these individuals may have been peculiarly sensitive to that type of effect is possible, but theoretical, and should not mitigate against either warning individuals of the possibility of such an effect, or stimulating research on this subject.

Some of the quotes I have read from testimony to E.P.A. on this matter lead me to suspect that the case in California and the issue itself may have been misrepresented. The case is currently been prepared for publication, and will be made available to E.P.A. at the earliest possible date, if you so desire.

In spite of a misquote you may have read on the UPI wire, we are in basic agreement on the data on carcinogenesis and teratogenesis. Our recommendations regarding broadcast application (page 32) is in keeping with your reference to individual states imposing restrictions on 2,4-D use in order to cut down on drift potential. Copies of release and report are enclosed.

I would appreciate any comments, and would be glad to try and answer any questions you might have.

Sincerely,

/s/ per conversation with Dr. Rosenberg 7/8/80

Jon Rosenberg, M.D.
Public Health Medical Officer
Hazard Alert System

Enclosure

jr:vk

CC: Kathleen Acree
Don Vial
Don Lyman
Richard Wade

DEPARTMENT OF
HEALTH SERVICES
714 P STREET, SACRAMENTO, CA, 95814

NEWS NEWS

20 June 1980

FOR RELEASE: On or after Tuesday, June 24, 1980

CONTACT: Elinor Blake
(415) 540-2115
Hazard Alert System

SUBJECT: 2,4-D

One of the most widely used plant-killing chemicals in the country may cause long lasting nerve damage, according to a report prepared by the Hazard Alert System (HALTS), a unit of the California Departments of Health Services and Industrial Relations.

The herbicide, 2,4-dichlorophenoxyacetic acid (2,4-D), is sprayed by airplane to prevent the growth of unwanted trees and brush in timberlands, and by hand to control weeds on roadsides, railroad tracks and waterways. It is also used on some fruit and grain crops. Approximately 1,000 tons of about 30,000 tons of 2,4-D produced annually in the United States are used in California alone.

Persons exposed to the chemical include those involved in its manufacture and formulation; agriculture, forestry workers and others involved directly in application; and persons in the immediate vicinity of spraying through spray drift, surface residue and water contamination. Herbicides containing 2,4-D are sold over the counter and are readily available to home gardeners, though a use permit is required in California for purchases of more than a quart.

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Estimations of the number of people exposed to 2,4-D are not available. The HALTS report takes a comprehensive look at earlier studies concerning 2,4-D's potential for causing cancer and birth defects, and documents the herbicide's potential for causing nerve damage.

2,4-D was also a major ingredient of Agent Orange, used by the United States armed forces to destroy forests in Vietnam. Two thousand Vietnam veterans have filed claims with the Veterans Administration, arguing that exposure to Agent Orange has left them with a variety of illnesses, reproductive problems and disabilities.

The Hazard Alert System, which evaluates the health effects of toxic substances in California's workplaces, has found six cases in the scientific literature in which people came into skin contact with 2,4-D while applying it, did not wash it off, and began showing signs of nerve damage one to two weeks later. The HALTS staff has documented a seventh recent case in which a California forestry worker suffered severe paralysis after accidentally spraying the herbicide on his face and neck.

In nearly all the cases, the poison victims developed nausea and other flu-like symptoms within four days after getting 2,4-D on their skin. A week or two later they developed tingling or numbness in their toes and fingers, followed by weakness of their arms and legs and, for some, virtually complete arm and leg paralysis.

The six men and one woman (who had kneeled in her garden just after spraying there) partially recovered over weeks and months, with medical treatment. However, the report notes, some damage has lasted for years and is probably permanent.

Animal tests suggest a potential risk of cancer and a possible low-level hazard of birth defects from 2,4-D, according to the HALTS report. Until further tests determine whether the chemical does in fact pose a cancer hazard, the

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report recommends that human exposure to 2,4-D be kept to the minimum. The report says that methods of application that could directly expose the general population, such as airplane spraying when drift may expose nearby persons, should be strongly discouraged.

Jon Rosenberg, M.D., a toxicologist and the report's principal author, urges that "Anyone who uses 2,4-D, at work or at home, should take special care not to get it on their skin or clothing. People who do come in contact with it should wash it off immediately with soap and water, and remove any contaminated clothing. If a person gets nausea, stomach cramping, diarrhea or vomiting within one to four days after exposure, he or she should consult a physician immediately."

The report recommends that 2,4-D product labels be changed to more adequately warn users of the herbicide's hazards and how to protect against them. It also recommends further research to better estimate the dangers 2,4-D poses to health.

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